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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,997	12/24/2003	Yukio Nihei	245553US0CONT	9427
22850	7590	02/09/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER GEMBEH, SHIRLEY V	
			ART UNIT	PAPER NUMBER
			1618	
			NOTIFICATION DATE	DELIVERY MODE
			02/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/743,997	Applicant(s) NIHEI ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-42 and 50-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-42 and 50-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/17/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The response filed on **11/17/2008** has been entered.
2. Applicant's arguments filed 11/17/08 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 39-42 and 50-56 are pending in this office action. Claims 39 and 41 are currently amended.
5. The objection of claim 39 is withdrawn due to the amendment of the claims.
6. The information disclosure statement (IDS) submitted on 11/17/08 is acknowledged and has been reviewed.
7. The rejection of claims 39-42 and 50-56 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn due to Applicants argument and supporting evidence given on pages 5-8 of the remarks.

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8. Claims 39-42 and 50-56 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nihei et al. (1999), and Hori et al. ,(2001) in view of Fex et al., (US 3,732,260) and Sugawara et al., (US 6,458,347) for the reasons made of record in Paper No. 20080617. It should be noted that Applicants remarks to 6/17/08 does not correlate to the rejection made on the 6/17/08. Claims rejected in office action 20080617 are 39-42 and 50-56, and not the claims recited in the remarks (i.e., claims 1, 11-15, 30, 32, 35-42, and 44-48). Below please find Examiner's response as appropriate to the claims. It is also correctly pointed out that the body of the rejection contained mistyped claims.

Applicant argues that the combination of Nihei, Hori, Fex and Sugawara would not have resulted in the claimed invention. Next, Applicant argues that there are practical and very real limitations on the medicinal use of AC-7700 and for the first time Applicant have shown that the safety zone of AC-7700 can be expanded while maintaining anti-tumor effect. Applicant also relies on unexpected result to overcome the obviousness rejection.

In response, Applicant's argument is not persuasive because Nihei clearly teaches that AC-7700 maintained activity against solid tumors when combined with dexamethasone, (as it relates to instant claim 39, see page 1023, last four lines of lft.col.). It is clear that the end result of the intended use is for the treatment of cancers/tumors. Claim 39 has no limitation as to the population being treated, therefore given the broadest claim interpretation, treating cells is well with the purview of the

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skilled artisan. Nonetheless, Nihei makes it obvious that humans may be treated, (see page 1022, last para, and rt. col.).

As to the arguments that there are practical and very real limitations on the medicinal use of AC-7700 and comments on the safety zone of AC-7700, these arguments are found not persuasive because these limitations are not recited in the claims.

In addressing any potential unexpected results, it should be noted that the results are not commensurate in scope with the claimed invention. The claims recite a combination of drugs, and Applicant's figures show tumors treated with and without dexamethasone with dosages at only 1 point with 1/mg/kg dexamethasone and 10 mg/kg AC-7700. In contrast, the claims recite wide ranges of dexamethasone and AC-7700 as 0.1-10000 mg. In order to show an unexpected result, Applicant should note that there are three major points that should be considered:

the unexpected result must truly be unexpected, it must be commensurate in scope (show a trend representing the scope), and lastly, a direct comparison with the closest prior art of record should be provided.

As stated in Ex parte Gelles 22 USPQ 2d 1318 (at 1319):

"The evidence relied upon also should be reasonably commensurate in scope with the subject matter claimed and illustrate the claimed subject matter "as a class" relative to the prior art subject matter."

Thus, Applicant has not shown that the results are truly unexpected and are commensurate in scope with that claimed .

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
1/23/08

/Robert C. Hayes/
Primary Examiner, Art Unit 1649